Subpart B—Specific Tolerances for Residues of New Animal Drugs

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556.34 Albendazole
556.36
       Altrenogest.
556.38
      Amoxicillin
556.40
       Ampicillin.
556.50
      Amprolium.
556.52
       Apramycin.
556.60
      Arsenic
556.70 Bacitracin.
556 100 Carbadox
556.110
       Carbomycin.
556.113
       Ceftiofur.
556.115
        Cephapirin.
556.120
        Chlorhexidine.
556.150
        Chlortetracycline.
556.160
        Clopidol.
556.163
        Clorsulon
556.165
        Cloxacillin.
556.167
        Colistimethate.
556.169
        Danofloxacin.
556.170
        Decoguinate.
556.180
        Dichloryos.
556.185
        Diclazuril.
556.200
        Dihydrostreptomycin.
556.225
        Doramectin.
556.226
        Enrofloxacin.
556.227
        Eprinomectin.
556.230
        Erythromycin.
        Estradiol and related esters.
556.240
556.260
        Ethopabate.
556.273
        Famphur.
556.275
        Fenbendazole.
556.277
        Fenprostalene.
556.283
        Florfenicol.
556.286
        Flunixin.
556.292
        Gamithromycin.
556.300
        Gentamicin sulfate.
556.304
        Gonadotropin.
556.308
        Halofuginone hydrobromide.
556.310
        Haloxon.
556.330
        Hygromycin B.
556.344
        Ivermectin.
556.346
        Laidlomycin.
556.347
        Lasalocid.
556.350
        Levamisole hydrochloride.
556.360
        Lincomycin.
556.375
        Maduramicin ammonium.
556.380
        Melengestrol acetate.
556.410
        Metoserpate hydrochloride.
556.420
        Monensin.
556.425
        Morantel tartrate.
556.426
        Moxidectin.
556.428
        Narasin.
556.430
        Neomycin.
556.440
        Nequinate.
556,445
        Nicarbazin.
556.460
        Novobiocin.
556.470
        Nystatin.
556.480
        Oleandomycin.
        Ormetoprim.
556,490
556,495
        Oxfendazole.
556,500
        Oxytetracycline.
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556.510

556.513

Penicillin.

Piperazine. 556.515 Pirlimycin.

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556.540 Progesterone
556.560
        Pyrantel tartrate.
556.570
        Ractonamine.
        Robenidine hydrochloride.
556.580
556.592
        Salinomycin.
556.597
        Semduramicin.
556.600
        Spectinomycin.
556.610
        Streptomycin.
556.620
        Sulfabromomethazine sodium.
       Sodium
556.625
                         sulfachloropyrazine
   monohydrate.
556.630
        Sulfachlorpyridazine.
        Sulfadimethoxine.
556.640
556.650
        Sulfaethoxypyridazine.
556.660
        Sulfamerazine.
556.670
        Sulfamethazine.
556.685
        Sulfaquinoxaline.
556.690
        Sulfathiazole.
556.700
        Sulfomyxin.
556.710
        Testosterone propionate.
556.720
        Tetracycline.
        Thiabendazole.
556.730
556.733
        Tildipirosin.
556.735
        Tilmicosin.
556.738
        Tiamulin.
556.739
        Trenbolone.
556.740
        Tylosin.
556.741
        Tripelennamine.
556.745
        Tulathromycin.
556.748
        Tvlvalosin.
556.750
        Virginiamycin.
556.760
        Zeranol.
556.765
        Zilpaterol.
556.770
       Zoalene.
  AUTHORITY: 21 U.S.C. 342, 360b, 371.
 SOURCE: 40 FR 13942, Mar. 27, 1975, unless
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Subpart A—General Provisions

otherwise noted.

§556.1 General considerations; tolerances for residues of new animal drugs in food.

- (a) Tolerances established in this part are based upon residues of drugs in edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug shall result in a conclusion either that:
- (1) Finite residues will be present in the edible products—in which case a finite tolerance is required; or
- (2) It is not possible to determine whether finite residues will be incurred but there is reasonable expectation that they may be present—in which case a tolerance for negligible residue is required; or
- (3) The drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, has

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been shown to induce cancer in man or animal; however, such drug will not adversely affect the animals for which it is intended, and no residue of such drug will be found by prescribed methods of analysis in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal—in which case the accepted method of analysis shall be published or cited, if previously published and available elsewhere, in this part; or

- (4) It may or may not be possible to determine whether finite residues will be incurred but there is no reasonable expectation that they may be present—in which case the establishment of a tolerance is not required; or
- (5) The drug is such that it may be metabolized and/or assimilated in such form that any possible residue would be indistinguishable from normal tissue constituents—in which case the establishment of a tolerance is not required.
- (b) No tolerance established pursuant to paragraph (a)(1) of this section will be set at any level higher than that reflected by the permitted use of the drug.
- (c) Any tolerance required pursuant to this section will, in addition to the toxicological considerations, be conditioned on the availability of a practicable analytical method to determine the quantity of residue. Such method must be sensitive to and reliable at the established tolerance level or, in certain instances, may be sensitive at a higher level where such level is also deemed satisfactory and safe in light of the toxicity of the drug residue and of the unlikelihood of such residue's exceeding the tolerance.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

$\S 556.34$ Albendazole.

- (a) Acceptable daily intake (ADI). The ADI for total residues of albendazole is 5 micrograms per kilogram of body weight per day.
- (b) *Tolerances*. The tolerances for albendazole 2-aminosulfone (marker residue) are:
- (1) Cattle—(i) Liver (target tissue): 0.2 parts per million (ppm).
 - (ii) Muscle: 0.05 ppm.

- (2) Sheep—(i) Liver (target tissue): 0.25 ppm.
 - (ii) Muscle: 0.05 ppm.
- (3) Goat—(i) Liver (target tissue): 0.25 ppm.
 - (ii) [Reserved]
- (c) Related conditions of use. See §520.45 of this chapter.

[64 FR 1504, Jan. 11, 1999, as amended at 73 FR 11027, Feb. 29, 2008]

§ 556.36 Altrenogest.

- (a) Acceptable Daily Intake (ADI). The ADI for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.
- (b) Tolerances—(1) Swine—(i) Liver (the target tissue). The tolerance for altrenogest (the marker residue) is 4 parts per billion (ppb).
- (ii) *Muscle*. The tolerance for altrenogest (the marker residue) is 1 ppb.
- (2) [Reserved]

[68 FR 62007, Oct. 31, 2003]

§556.38 Amoxicillin.

A tolerance of 0.01 part per million is established for negligible residues of amoxicillin in milk and in the uncooked edible tissues of cattle.

[49 FR 45422, Nov. 16, 1984]

§ 556.40 Ampicillin.

A tolerance of 0.01 p/m is established for negligible residues of ampicillin in the uncooked edible tissues of swine and cattle and in milk.

§556.50 Amprolium.

Tolerances are established as follows for residues of amprolium (1-(4-amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride):

- (a) In the edible tissues and in eggs of chickens and turkeys:
- (1) 1 part per million in uncooked liver and kidney.
- (2) 0.5 part per million in uncooked muscle tissue.
 - (3) In eggs:
 - (i) 8 parts per million in egg yolks.
- (ii) 4 parts per million in whole eggs.
- (b) In the edible tissues of calves:
- (1) 2.0 parts per million in uncooked fat.
- (2) 0.5 part per million in uncooked muscle tissue, liver, and kidney.